



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

March 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 38

Ann Renz
Interim President, Operations & Administration
Allina Medical Clinic Administration
8450 City Centre Drive
Woodbury, Minnesota 55125

Dear Ms. Renz:

On February 19, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your Champlin Medical Center facility at 11269 Jefferson Highway, Champlin, MN (FDA Certificate #188284). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, non-compliances were documented at your facility as follow:

Repeat Level 2 Non-compliance:

1. The written procedure for handling consumer complaints is inadequate in that all mandated elements are not addressed.

Note: This was also cited during the February 2, 2000, inspection. The topic was further addressed in a March 6, 2000, letter to your Lead Interpreting Physician, ~~~~~ and Radiological Technologist ~~~~~ on ~~~~~ A copy of this letter was also faxed to ~~~~~ on March 17, 2000.

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Level 2 Non-compliance:

2. Phantom QC records were missing for at least two weeks but less than four weeks for mammography system (Mammo Room; ACR designation = Unit 2).

Repeat Level 3 Non-compliance:

3. The QA program is inadequate. For the Champlin Medical Center site the missing or incomplete item(s) are listed below:

Personnel responsibilities

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

FDA acknowledges a response by Margaret Mickelson of the inspected site. It was postmarked February 28, 2001. That response adequately addressed both the Repeat Level 2 and Level 2 non-compliances.

The response further addressed a Repeat Level 3 non-compliance involving the designation of personnel responsibilities. Please update this listing to include a reference to the site's "audit interpreting physician."

The intent of this letter is to formally advise senior management of the Repeat Level 2 findings.

Please forward a copy of the revised list of personnel responsibilities within 15 days to Radiological Health Specialist Thomas W. Garvin, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305. A submission by fax, (414) 771-7512, is also acceptable.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does

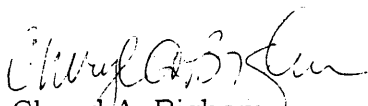
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not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,



Cheryl A. Bigham
Acting Director
Minneapolis District

TWG/ccl

SLY

xc:

Lead Interpreting Radiologist

c/c

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